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PATENT  
Atty. Docket No. 2500 DIV2 CON2 DIV3 CON7  
(203-3515 DIV2 CON2 DIV3 CON7)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS: Peter M. Bonutti EXAMINER: Michael H. Thaler  
SERIAL NO.: 10/743,197<sup>2</sup> GROUP: 3731  
FILED: December 22, 2003 DATED: March 17, 2006  
FOR: FLUID OPERATED RETRACTORS

Mail Stop Appeal Brief  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL OF APPELLANTS' BRIEF**

Sir:

Enclosed please find APPELLANTS' BRIEF in triplicate.

The Commissioner is authorized to charge Deposit Account No. 21-0550 in the amount of \$500.00, which is the appeal fee. Also, in the event any additional extensions of time are required, please treat this paper as a petition to extend the time as required and charge Deposit

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Dated: March 17, 2006

  
Dana A. Brussel

Account No. 21-0550. TWO (2) COPIES OF THIS SHEET ARE ENCLOSED.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dana A. Brussel", written over a horizontal line.

Dana A. Brussel

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**APPEAL BRIEF**

Sir:

This is an appeal from a Final Office Action mailed on July 15, 2005 in connection with the above-identified application. This Appeal Brief is accompanied by the requisite fees set forth in 37 C.F.R. § 41.20 (b) (2).

**I. REAL PARTY IN INTEREST**

The real party in interest for this application is General Surgical Innovations, Inc., a wholly owned subsidiary of Tyco Healthcare Group, LP.

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Dated: March 17, 2006

  
Dana A. Brussel

## **II. RELATED APPEALS AND INTERFERENCES**

A Notice of Appeal and a request for a Pre-Appeal Brief Panel Review were filed on February 3, 2006 for U.S. Patent Application Serial Number 10/662,923, which is the parent application for the presently appealed application. Appellant, appellant's legal representative, and/or the assignee of appellant's interest in the above-identified application are not aware of any other related appeals, interferences, or judicial proceedings which may be related to, directly affect, or be directly affected by, or have a bearing on any decision by the Board of Patent Appeals and Interferences in this Appeal.

## **III. STATUS OF CLAIMS**

The instant application was originally filed with nine (9) claims. Independent claim 1 and dependent claims 2-4 and 7 are pending in this application and are involved in this Appeal. Each of these claims stands finally rejected as set forth in the Office mailed on July 15, 2005. An accurate copy of claims 1-4 and 7 is provided in the Claims Appendix.

## **IV. STATUS OF AMENDMENTS**

The Advisory Action mailed on January 13, 2006 indicated that the Reply to the Final Office Action, which was filed on December 14, 2005, had been considered, but did not place the application in condition for allowance.

A Pre-Appeal Brief Request for Review was mailed on January 13, 2005 to present remarks in support of the claims pending in the instant application. A Notice of Decision from the Pre-Appeal Brief Review was mailed on February 3, 2006. According

to the Notice of Decision, the application remains under appeal because there is at least one factual issue for appeal. The panel determined that claims 1-4 and 7 are still rejected.

#### **V. SUMMARY OF CLAIMED SUBJECT MATTER**

Claim 1 is directed towards an apparatus having a rigid shaft. The shaft has open first and second ends defining a lumen therebetween. An inflatable bladder is disposed at the distal end and is in fluid communication with the lumen (Specification page 13, line 23 - page 14, line 2). Upon inflation, the inflatable bladder has the shape of a wedge and separates adjacent portions of bone tissue thereby creating a working space (Specification page 18, lines 14-19).

#### **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The following issues are on appeal:

whether the apparatus of claims 1-4 and 7 is anticipated by U.S. Patent No. 3,417,745 to Sheldon (hereinafter "Sheldon") which discloses an endoscope; and

whether the apparatus of claims 1-4 and 7 is obvious over the endoscope disclosed in Sheldon.

#### **VII. ARGUMENT**

In rejecting the present claims under 35 U.S.C. § 102 (b) and 103 (a), the Examiner has misconstrued the art cited against the pending claims.

The patentability of two separate groups of claims are separately argued herein:  
(1) claim 1 that recites an apparatus having a rigid shaft with open first and second ends

defining a lumen therebetween, an inflatable bladder disposed at the distal end and in fluid communication with the lumen, wherein inflation of the inflatable bladder separates adjacent portions of bone tissue thereby creating a working space; and (2) claim 7 that recites an apparatus including a cannula with a passage that receives the shaft for deploying the inflatable bladder at a target site in tissue.

**A. Sheldon Fails To Anticipate Or Render Obvious The Recited Apparatus Having A Lumen Defined By Open Ends With An Inflatable Bladder That Separates Adjacent Portions Of Bone**

The Examiner has rejected claim 1 as being anticipated by or, in the alternative, as obvious over Sheldon. This rejection should be reversed.

Independent claim 1 recites an apparatus having a rigid shaft with open first and second ends defining a lumen therebetween and an inflatable bladder disposed at the distal end that is in fluid communication with the lumen, wherein inflation of the inflatable bladder separates adjacent portions of bone tissue, thereby creating a working space.

Contrary to the allegations made by the Examiner, Sheldon does not anticipate or render obvious any of the claims on appeal because Sheldon fails to disclose or suggest a shaft having open first and second ends defining a lumen therebetween with an inflatable bladder disposed at the distal end of the shaft. In addition, Sheldon fails to disclose or suggest that the inflatable member, upon inflation, has the shape of a wedge and separates adjacent portions of bone tissue to create a working space. In particular, Sheldon discloses a device having a hollow tube with a closed distal end wherein at least one window is included in the closed distal end. An inflatable member is attached along the

exterior of the device such that it does not encase the windows. In particular, a separate inflation tube extends along the exterior of Sheldon's device and is fluidly coupled to the inflatable member. Sheldon expressly states that the "main purpose of this invention is to provide means for the diagnosis of a herniated ("slipped") intervertebral disc."<sup>1</sup>

According to Sheldon's disclosure, "[t]he inflation of the member 57 causes separation of the examined part from the distal end of the spinescope. This allows proper functioning of the optical system. After this has been accomplished the spinescope may be advanced into the newly created space."<sup>2</sup> In addition, Sheldon discloses that the inflatable member is provided to displace the fluid and soft tissue, such as disc or nerve tissue, that exists in the extra-dural space of the spinal canal.<sup>3</sup> Sheldon specifically discloses that:

Once the puncture of the dura is made, the new spinescope can enter the extra-dural space and it may be advanced towards the inter-vertebral foramen or to inter-vertebral space where the herniated disc or the compressed root of the nerve may be found. In some cases the space for viewing must be created artificially so that the optical system can operate properly. For this purpose a small inflatable member is attached to the tip of the spinescope, as was explained above.<sup>4</sup>

Further still, Sheldon discloses that an inflatable member is mounted at the distal end of the spinescope and "displaces the turbid spinal fluid and produces thereby a clear field of vision."<sup>5</sup> Contrary to the Applicant's apparatus for separating adjacent portions of bone tissue, Sheldon specifically discloses that the spinescope includes an inflatable member for urging soft tissue away from the distal end of the spinescope. Sheldon's specific

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<sup>1</sup> U.S. Patent No. 3,417,745 to Sheldon at Column 1, lines 51-53.

<sup>2</sup> *Id.* at Column 9, lines 5-9.

<sup>3</sup> *Id.* at Column 9, lines 20-23.

<sup>4</sup> *Id.* at Column 9, lines 62-70.

<sup>5</sup> *Id.* at Column 8, lines 53-54.

disclosure of displacing turbid spinal fluids or moving soft tissues (i.e. disc or nerve) to provide a clearer optical viewing path through the window does not suggest moving or separating adjacent portions of bone tissue with an apparatus having an inflated inflatable member attached thereto.

Nowhere in Sheldon is it disclosed or suggested that the spinescope includes an open first end or an open second end defining a lumen therebetween, or that the inflatable member is in communication with the lumen. Sheldon discloses that one end of the spinescope includes a viewing window and specifically illustrates (see Figures 2, 2A-E, 2G, 3, 3A, and 5) that the viewing window forms part of the closed end of the spinescope. Rather than disclosing or suggesting a shaft having an open first end and an open second end, Sheldon specifically discloses a device wherein one end of the device is closed and the inflatable member is attached along the exterior of the device.

Thus, Sheldon fails to anticipate or render obvious claim 1 and the rejection of claim 1 under 35 U.S.C. § 102 (b) and 103 (a) should be reversed.

**B. Sheldon Fails To Anticipate Or Render Obvious The Recited Apparatus Having Cannula With A Passage That Receives The Shaft For Deploying The Inflatable Bladder At A Target Site In Tissue**

The Examiner has rejected claim 7 as being anticipated by or, in the alternative, as obvious over Sheldon. This rejection should be reversed.

Claim 7 depends from independent claim 1 and recites that the apparatus includes a cannula having a passage that receives the shaft to deploy the bladder at a target site in tissue.

Contrary to the assertions made by the Examiner, Sheldon fails to disclose or suggest a cannula. Sheldon discloses that the disclosed spinescope may be used in combination with a spinal needle. According to Sheldon, the spinal needle has a shaft with a tip and a pointed distal end. Moreover, the "shaft 5e is cut through one of its walls creating thereby two valve-like half-walls 6 and 6a with [sic] are locked together at the proximal end of the needle outside the examined body."<sup>6</sup> As shown and disclosed in Sheldon, the needle has a pointed, closed distal end (see Figures 1 and 1A). Sheldon's spinal needle is used to house the spinescope after the needle is inserted into the spinal canal. The needle halves may be spread apart to enlarge the lumen of the needle to accommodate a larger diameter spinescope, after which they are locked together again.<sup>7</sup> Nowhere in Sheldon is it disclosed or suggested that the bladder on the shaft may be deployed at a target site in tissue through a passageway in a cannula. Rather, Sheldon specifically discloses that the spinescope is maintained within the spinal needle.<sup>8</sup>

In contrast to Sheldon's disclosed spinal needle, the Applicant's apparatus includes a cannula having a passage for deploying the bladder at a target site in tissue. Sheldon fails to disclose or suggest that a cannula having a passageway for deploying a bladder at a target site.

Thus, Sheldon fails to anticipate or render obvious claim 7 and the rejection of claim 7 under 35 U.S.C. § 102 (b) and 103 (a) should be reversed.

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<sup>6</sup> *Id.* at Column 3, lines 21-24.

<sup>7</sup> *Id.* at Column 3, lines 28-36.

<sup>8</sup> *Id.*

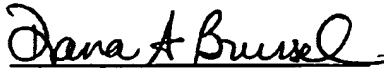
**C. Conclusion**

In view of the foregoing analysis and remarks, it is clear that the apparatus having a rigid shaft with open first and second ends defining a lumen therebetween and an inflatable bladder that, upon inflation, separates adjacent portions of bone tissue thereby creating a working space as recited in independent claim 1 and the cannula having a passage that receives the shaft to deploy the bladder at a target site in tissue as recited in claim 7 are neither anticipated nor rendered obvious by Sheldon. For at least the foregoing reasons, it is respectfully submitted that:

the apparatus of claims 1-4 and 7 is not anticipated by Sheldon and this rejection should be reversed; and

the apparatus of claims 1-4 and 7 is not obvious over the endoscopic instrument (i.e. the spinescope) disclosed in Sheldon and this rejection should be reversed.

Respectfully submitted,

  
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**VIII. CLAIMS APPENDIX**

1. An apparatus comprising:  
  
a rigid shaft having an open first end and an open second end defining a lumen therebetween; and  
  
an inflatable bladder disposed at the distal end and in fluid communication with the lumen, the inflatable bladder having the shape of a wedge upon inflation such that the inflatable bladder separates adjacent portions of bone tissue thereby creating a working space.
2. An apparatus as in claim 1, wherein the inflatable bladder does not stretch when fully inflated.
3. An apparatus as in claim 1, wherein the inflatable bladder operates at inflation pressures from 10 mmHg to 1000 mmHg.
4. An apparatus as in claim 3, wherein the inflatable bladder operates at inflation pressures from 100 mmHg to 1000 mmHg.
7. An apparatus as in claim 1, further comprising a cannula having a passage which receives the shaft to deploy the bladder at a target site in tissue.

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**IX. EVIDENCE APPENDIX**

None.

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**X. RELATED PROCEEDINGS APPENDIX**

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